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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002952995 for a patent by COCHLEAR LIMITED as filed on 29 November 2002.

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Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Controlled release of pharmaceuticals from an electrode array of a cochlear implant

The invention is described in the following statement:

Field of the Invention

The present invention relates to an implantable device and, in particular, to an implantable device for use in delivering pharmaceuticals to a cochlea following implantation of a cochlear electrode assembly.

Background of the Invention

Hearing loss, which may be due to many different causes, is generally of two types, conductive and sensorineural. Of these types, conductive hearing loss occurs where the normal mechanical pathways for sound to reach the hair cells in the cochlea are impeded, for example, by damage to the ossicles. Conductive hearing loss may often be helped by use of conventional hearing aid systems, which amplify sound so that acoustic information does reach the cochlea and the hair cells.

In many people who are profoundly deaf, however, the reason for deafness is sensorineural hearing loss. This type of hearing loss is due to the absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are thus unable to derive suitable benefit from conventional hearing aid systems, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve.

Cochlear implant systems have typically consisted of two key components, namely an external component commonly referred to as a processor unit, and an implanted internal component commonly referred to as a receiver/stimulator unit. Traditionally, both of these components have cooperated together to provide the sound sensation to an implantee.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds and particularly speech into a coded signal, a power source such as a battery, and an external antenna transmitter coil.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted receiver/stimulator unit situated within a recess of the temporal bone of the implantee. This transcutaneous transmission occurs through use of an inductive coupling provided between the external antenna transmitter coil which is positioned to communicate with an implanted antenna receiver coil provided with the receiver/stimulator unit. This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted receiver/stimulator unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted receiver/stimulator unit typically includes the antenna receiver coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal through a lead to an intracochlea electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

The electrode assembly is typically implanted through a cochleostomy formed in the cochlea and comprises an array of electrodes, with each electrode being arranged and constructed to deliver a cochlea stimulating signal within a preselected frequency range to an appropriate cochlea region. The electrical currents and electric fields from each electrode stimulate the cilia disposed on the modiolus of the cochlea. Several electrodes may be active simultaneously.

There have been a number of proposals for delivering bio-active substances to the cochlea that are beneficial in promoting acceptance of the electrode assembly within the cochlea and/or assisting in the function of the

auditory nerve. One such proposal is described in the present applicant's International Application No PCT/AU01/01479 which describes use of a lumen within the electrode assembly that delivers bioactive substances directly within the cochlea following implantation of the assembly.

The present invention provides an alternative system for delivering beneficial bio-active substances to the region of the cochlea of a patient and particularly an implantee of a cochlear implant.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

Generally, the present invention provides a device that is adapted to assist in the delivery of pharmaceutical treatment to surrounding tissue following the insertion and positioning of an electrode assembly. Typically, the electrode assembly is positioned in order to apply electrical stimulation to a target region of tissue via dedicated electrical stimulating electrodes. The present invention is applicable to all types of tissue stimulating devices such as cochlear implants, deep brain implants, spinal cord implants and any other implantable devices that treat neurosensory or motorsensory loss or dysfunction.

It is a preferred feature of the present invention to provide a device that is adapted to assist the cochlea in its recovery from trauma following the

insertion of an electrode assembly therein. The present invention is equally applicable to conventional straight electrode assemblies and electrode assemblies which are designed to conform with the inner wall of the cochlea.

According to a first aspect, the present invention is a drug delivery device comprising:

a resiliently flexible elongate member having a proximal end and a distal end for implantation within a body;

wherein at least a portion of said elongate member is comprised of a porous biocompatible material, at least some of the pores having at least one bio-active substance disposed therein prior to implantation, said at least one bio-active substance being adapted to migrate from the pores following implantation of the member

In this aspect, the resiliently flexible elongated member can form part of an implantable tissue-stimulating device having at least one electrode mounted thereon.

In another embodiment of this aspect, the drug delivery device can be separate to a tissue stimulating device but which acts in conjunction with said tissue stimulating device.

According to a second aspect, the present invention is an implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end and at least one electrode mounted thereon between said proximal and distal ends for delivering electrical stimulation;

wherein at least a portion of said elongate member is comprised of a porous biocompatible material, at least some of the pores having at least one bio-active substance disposed therein prior to implantation, said at least one bio-active substance being adapted to migrate from the pores following implantation of the member.

In a preferred embodiment of this invention, the device is a cochlear implant electrode assembly, with the elongate member adapted to be inserted through a cochleostomy formed in the cochlea and positioned therein.

In one embodiment, the elongate member can be comprised of one or more porous portions. In one embodiment, the porous portions can comprise the same material as the remainder of the elongate member but having a plurality of pores disposed therethrough. In one embodiment, the porous portions can comprise the same material as the remainder of the elongate member but which has undergone a processing step to render the portions foraminous. In another embodiment, a majority, or the entire body, of the elongate member can be porous.

In one embodiment of this aspect, the elongate member can be formed from a silicone material.

In yet another embodiment, the porous portions can be formed from a different material to that of the remainder of the elongate member. In one embodiment, the porous portions can act as electrodes for delivering electrical stimulation at the site of implantation of the elongate member. In this embodiment, the electrodes can be formed from a suitable porous metallic material. The metallic material can be a suitable porous platinum. In another embodiment, the porous portions can be formed from a suitable porous metallic material, such as a porous platinum, mounted in the elongate member but where the portions are not adapted to deliver electrical stimulation.

In one embodiment, all of the electrodes mounted to the elongate member can be formed from the suitable metallic material, such as a porous platinum. In another embodiment, only some of the electrodes can be porous, with some of the electrodes being formed from a suitable relatively non-porous metallic material, such as platinum.

In a still further embodiment, the device can further comprise a sheath comprised at least in part of a porous material disposed over at least a portion of the elongate member. In a preferred embodiment, a majority of and, more preferably, the entire elongate member can be sheathed in the porous material. Still further, at least a majority and, more preferably, the entire sheath is formed of a porous material.

According to a third aspect, the present invention is an implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end and at least one electrode mounted thereon between said proximal and distal ends for delivering electrical stimulation; and

a sheath comprised at least in part of a porous material disposed over at least a portion of the elongate member;

wherein at least some of the pores of the sheath have at least one bio-active substance disposed therein prior to implantation, said at least one bio-active substance being adapted to migrate from the pores following implantation of the member.

According to a fourth aspect, the present invention is an implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end; and

at least one electrode mounted on the elongate member between said proximal end and said distal end for delivering electrical stimulation;

wherein at least one of said at least one electrode is comprised of a porous biocompatible material, at least some of the pores having at least one bio-active substance disposed therein prior to implantation, said at least one bio-active substance being adapted to migrate from the pores following implantation of the member.

In this aspect, said at least one electrode can be formed from a suitable porous electrically conductive material. The electrically conductive material can be a suitable porous metallic material. The metallic material can be a suitable porous platinum. In one embodiment of this aspect, all of the electrodes mounted to the elongate member can be formed from the suitable electrically conductive material, such as a porous platinum. In another embodiment, only some of the electrodes can be porous, with some of the electrodes being formed from a suitable relatively non-porous metallic material, such as platinum.

In each of the above aspects, each pore of the porous portion can be an individual pore within the portion, making no interconnection with another pore

in the portion. In this embodiment, at least some or each of the pores can be aligned and/or equally spaced with respect to each other. In another embodiment, some of the pores can be interconnected with at least some other pores within the porous portion. In yet another embodiment, the pores can be arranged in a random order with some of the pores being interconnected with at least some of the other pores and some of the pores not interconnected with any of the other pores.

In a further embodiment, at least some of the pores or each pore of the porous portion can be at least substantially uniform in cross-sectional shape relative to each other. In another embodiment, the pores can vary in cross-sectional shape from one to at least some of the others.

In a still further embodiment, at least some of the pores or each pore of the porous portion can be substantially uniform in diameter. In another embodiment, the pores can vary in diameter from one to at least some of the others.

In yet another embodiment, at least some of the pores or each pore of the porous portion can be of a substantially constant diameter along its length. In another embodiment, at least some of the pores or each pore can vary in diameter along its length.

In a still further embodiment, at least some of the pores or each pore of the porous portion can have a substantially uniform cross-sectional shape along its length. In another embodiment, at least some of the pores or each pore can vary in cross-sectional shape along its length.

In yet another embodiment, at least some of the pores or each pore of the porous portion can be of a substantially constant length. In another embodiment, at least some of the pores or each pore can vary in length relative to at least some of the others in that portion. In one embodiment, at least some of the pores can have relatively extended lengths compared to other pores in that portion.

In still another embodiment, at least some of the pores or each pores of the porous portion can be at least substantially linear. In another embodiment, at least some of the pores or each pores of the porous portion can be non-linear.

In a still further embodiment, at least some of the porous portions or each porous portion can have substantially the same of pores per unit area. In another embodiment, at least some of the porous portions or each porous portion can have differing number of pores per unit area relative to that of at least some of the other porous portions.

In yet another embodiment, at least some of the pores in one, some or each of the porous portions can have relatively smooth internal walls. In another embodiment, at least some of the pores in one, some or each of the porous portions can have rippled internal walls. The ripples can have a suitably small dimension to preferably at least substantially prevent wetting of the cavities thereby minimising friction between the bioactive substance and the walls.

In one embodiment, the nature of the porosity between separate porous portions of the device may be the same or vary from one to at least some or all of the other portions. For example, the dimension of the pores of a porous portion relatively close to the distal end of the elongate member may be different to the dimensions of the pores of a porous portion that is relatively close to the proximal end of the elongate member. In this embodiment, the portion relatively closer to the distal end can have pores having a diameter and/or length greater than the pores of the porous portion relatively closer to the proximal end of the elongate member. In another embodiment, the relative porosity of different portions can be essentially random.

In a further embodiment, at least some of the pores of the porous portion can be preferably adapted to be at least substantially closed when the elongate member is at least substantially straight thereby preventing migration of any bioactive substance held within said at least some pores from these pores. On adopting a curved configuration, said at least some pores can be adapted to at least partially open allowing migration of the bioactive substance therefrom.

In one embodiment, the bioactive substances can be free to simply migrate from the pores of the porous portions following implantation of the device. In another embodiment, the bioactive substance can be dispersed in an ionic fluid that is preferably caused to migrate from the pores on application of a suitable electrical field thereto. In another embodiment, the bioactive substance can be dispersed in an ionic solution that is allowed to diffuse from the pores and/or be expelled therefrom under application of a suitable electric field.

In one embodiment, the bioactive substance can be dispersed in a suitable fluid. In one embodiment, the bioactive substance can comprise a steroid. In another embodiment, the bioactive substance can perform a function of reducing the resting neuron potential of neurons within the cochlea. The use of such substances can result in less energy being required to excite the neurons and cause stimulation. In yet another embodiment, the bioactive substance can perform a function of reducing bleeding or tissue growth or act as an antibiotic.

In a further embodiment, the elongate member of the stimulating device has a plurality of electrodes mounted thereon. The member can have a diameter of about 0.6mm. The member can also have a first configuration selected to allow said member to be inserted into an implantee's body, such as the cochlea, and a second configuration wherein said elongate member is adapted to apply a preselected tissue stimulation with the electrodes. In a further embodiment, the elongate member can have at least one intermediate configuration between said first and second configurations.

In a still further embodiment, at least a portion of the outer surface of the elongate member can have a coating of lubricious material. In a further embodiment, a substantial portion of the outer surface can have a coating of the lubricious material. In a still further embodiment, the entire outer surface of the elongate member can have a coating of the lubricious material.

The lubricious material preferably becomes lubricious on being brought into contact with a fluid, such as a saline solution. Still further, the coating

preferably becomes lubricious on being brought into contact with a body fluid, such as cochlear fluid.

In one embodiment, the lubricious material is selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It is envisaged that other similar materials could also be used. It is envisaged that the lubricious material can also be impregnated with the bio-active substance allowing the coating to perform a dual role. The rate of delivery of the bio-active substance can be programmed by design of the coating structure.

In yet another embodiment, the device can include a stiffening element made of a second material relatively stiffer than the resiliently flexible material of the elongate member. The stiffening element can be adapted to bias the elongate member into the first configuration.

In a preferred embodiment, the second configuration of the elongate member is curved. More preferably, the elongate member adopts a spiral configuration when in the second configuration.

The elongate member is preferably preformed from a plastics material with memory and is preformed to the second configuration. In a preferred embodiment, the first configuration is preferably substantially straight. More preferably, the first configuration is straight.

In a preferred embodiment, the elongate member is formed from a suitable biocompatible material. In one embodiment, the material can be a silicone, such as Silastic MDX 4-4210 or other biocompatible silicones. In another embodiment, the elongate member can be formed from a polyurethane or similar material.

In one embodiment, the stiffening element can comprise a metallic stylet, or a stylet-like element formed from any other suitable stiffening material, extending through a lumen in the elongate member. In one embodiment, the wire can be formed from a biocompatible metal, a biocompatible metallic alloy

or a biocompatible relatively stiff plastic. In a preferred embodiment, a metal stylet can be formed from platinum.

The present invention provides a surgeon with an implantable component of a cochlear implant electrode array that can assist with the delivery of one or more bio-active substances to a position within the cochlea following implantation of the component. The substances that can be delivered by the present device include substances that are adapted to promote healing, substances that prevent bleeding or at least excessive bleeding, and also substances that prevent the growth of tissue, including scar tissue, in the cochlea following implantation. Pharmaceutical compounds such as anti-inflammatories and antibiotics can also be delivered by the present device.

It is also envisaged that substances that assist in reducing the resting potential of the surrounding neurons can also be delivered by the present invention. It should be appreciated that during neural stimulation the neurons propagate an action potential through the response of transmembrane ion channels to local electrical fields. By delivering a substance that elicits a change in the transmembrane potential, the resting neural membrane potential can be moved towards the activation potential resulting in a lowering of the energy required to be delivered to activate the neuron. This also has the potential to reduce the power required by the stimulation device as well as increase the specificity of the electrical stimulation and restore the stochastic response of the neurons.

The device can be adapted to only provide delivery of a bio-active substance to the preferred site for a particular period following implantation. This period may comprise any period of time from a few hours or days to a few weeks or even months.

Once implanted, the electrodes can receive stimulation signals from a stimulator device. The stimulator device is preferably electrically connected to the elongate member by way of the electrical lead. The lead can include the one or more wires extending from each electrode of the array mounted on the elongate member.

In one embodiment, the lead can extend from the elongate member to the stimulator device or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator means, required to connect the wires extending from the electrodes to the stimulator means. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes and the stimulator means. In this case, the body of the substance delivery means is preferably positioned around the lead prior to attachment of the lead to the stimulator device.

The stimulator device is preferably positioned within a housing that is implantable within the implantee. In the application of the present invention to cochlear implants, the housing for the stimulator device is preferably implantable within the bony well in the bone behind the ear posterior to the mastoid.

When implantable, the housing preferably contains, in addition to the stimulator device, a receiver device. The receiver device is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the implantee.

Signals can preferably travel from the controller means to the receiver device and vice versa. The receiver device can include a receiver coil adapted to receive radio frequency (RF) signals from a corresponding transmitter coil worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver coil, the receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

In the application of the present invention to cochlear implants, the external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the implantee, however, other suitable locations can be envisaged, such as a lapel of the implantee's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted receiver/stimulator device using the transmitter and receiver coils. The implanted receiver/stimulator device demodulates the FM signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

For other applications beyond cochlear implants, the external controller can comprise a simple electronic unit capable of being programmed to perform a specific task, such as a predetermined stimulation pattern to a region of the brain or nerves in accordance with a trigger event, such as a sensed body condition or a patient-triggered action.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted receiver/stimulator device and the electrode array.

According to a further aspect, the present invention is a method of delivering at least one bioactive substance to a desired site of action within a cochlea using a device as defined herein, the method comprising the steps of:

forming a cochleostomy;

inserting the elongate member through the cochleostomy;

allowing or causing the bioactive substance to migrate from the elongate member into the cochlea.

In this aspect, the pores of the device are at least partially filled by dipping the elongate member in the bioactive substance for a suitable time period. This step can be performed immediately after manufacture of the

elongate member. In another embodiment, the step can be performed just prior to implantation of the member into the implantee.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

Fig. 1 is a pictorial representation of a prior art cochlear implant system;

Fig. 2 is a simplified view of one embodiment of an elongate member according to the present invention;

Fig. 3 is a simplified view of another embodiment of an elongate member according to the present invention;

Fig. 4 is a simplified view of still another embodiment of an elongate member according to the present invention;

Figs. 5a and 5b are simplified view of yet another embodiment of an elongate member according to the present invention;

Figs 6a and 6b are simplified views of yet still another embodiment of an elongate member according to the present invention;

Figs. 7a, 7b and 7c are views of different types of pores according to the present invention;

Fig. 8 depicts one type of porous structure for use in the present invention; and

Fig. 9 depicts another type of porous structure for use in the present invention.

Preferred Mode of Carrying out the Invention

Before describing the features of the present invention, it is appropriate to briefly describe the construction of one type of known cochlear implant system with reference to Fig. 1.

Known cochlear implants typically consist of two main components, an external component including a speech processor 29, and an internal component including an implanted receiver and stimulator unit 22. The external component includes a microphone 27. The speech processor 29 is, in this illustration, constructed and arranged so that it can fit behind the outer ear 11. Alternative versions may be worn on the body. Attached to the speech processor 29 is a transmitter coil 24 which transmits electrical signals to the implanted unit 22 via a radio frequency (RF) link.

The implanted component includes a receiver coil 23 for receiving power and data from the transmitter coil 24. A lead 21 extends from the implanted receiver and stimulator unit 22 to the cochlea 12 and terminates in an electrode array 20 that is passed through a cochleostomy and into the cochlea 12. The signals thus received are applied by the array 20 to the basilar membrane 8 and the nerve cells within the cochlea 12 thereby stimulating the auditory nerve 9. The operation of such a device is described, for example, in US Patent No. 4532930, the contents of which are incorporated herein by reference.

The array 20 typically comprises an elongate electrode carrier member having a plurality of electrodes mounted thereon. The elongate member is also typically preformed from a resiliently flexible silicone with memory and can be preformed to a curved configuration suitable for insertion in the scala tympani of a human cochlea 12. While an assembly that normally adopts a curved configuration when in a relaxed condition is typically preferred, it will be appreciated that the present invention also could be utilised with respect to assemblies that are normally straight when in a relaxed condition.

Still further, the array 20 typically has a lumen that, prior to insertion of the assembly 20 into the cochlea 12, can receive a substantially straight platinum stylet. Such a stylet typically has a stiffness that is sufficient to retain the silicone elongate member in a straight configuration.

As depicted, the electrode assembly 20 has an electrical lead 21 extending back to a receiver/stimulator unit 22. In considering this invention, it is to be understood that each electrode may have one or more wires electrically connected thereto and extending from each respective electrode 32 back through the lead 21 to the receiver/stimulator unit 22.

Various examples of elongate members according to the present invention are depicted in Figs 2 to 6b. Where electrodes are depicted in these drawings, it is to be understood that the electrodes are not necessarily shown to scale. A larger number of electrodes than that depicted can also be envisaged.

Fig. 2 depicts an elongate member 40 having a plurality of electrodes 41 which are formed from a biocompatible porous platinum material. In the depicted embodiment, each of the electrodes 41 are formed from this material and each adapted to deliver electrical stimulation to the cochlea following implantation. It will be appreciated that in another embodiment, only some of the electrodes 41 could be formed from the porous platinum material, with some of the electrodes being formed from a suitable relatively non-porous metallic material, such as platinum as traditionally used in cochlear implant electrode arrays. In this embodiment, the electrodes 41 have a bioactive substance disposed within the pores of the platinum material that is able to migrate from the electrodes 41 following implantation of the member 40.

Fig. 3 depicts another embodiment of an elongate member 50 again having a plurality of electrodes 41 which are formed from a biocompatible porous platinum material. In this embodiment, however, the elongate member is provided with a further set of porous platinum rings 51 that are mounted to the member. As depicted, the rings 51 can be disposed between the electrodes 41 mounted on the member. Other locations for the rings can be envisaged. In this embodiment, the rings 51, unlike the electrodes 41, are not adapted to deliver electrical stimulation to the auditory system 12, rather, the electrodes are electrically active but are adapted to create an electrical field to release a drug from the member. If they are electrically active then they can be considered to be electrically stimulating the cochlea but not necessarily delivering auditory stimuli thereto. Like the electrodes 41, the depicted rings 51

have a bioactive substance disposed within the pores of the platinum material that is able to migrate from the rings 51 following implantation of the member 50. In a further example, rings 51 may not deliver electrical stimulation to the auditory system immediately after implantation and their role is limited to release of drugs. Once the supply of drugs has been exhausted, the rings 51 revert to delivering electrical stimulation to the auditory system.

The electrical field required for the release of drugs may be created by stimulation in monopolar, bipolar, tripolar, etc mode.

In a further example, the stimulating electrodes are different from the drug delivering electrodes in either shape and/or in electrical connection. While Fig. 3 dep relatively non-porous platinum as is traditionally used in cochlear implant electrode arrays.

Fig. 4 depicts a still further embodiment of an elongate member 60 in which the material forming the body 61 of the member to which the electrodes 62 are mounted is formed of porous material, such as a porous silicone. The pores of the body 61 have a bioactive substance disposed therein that is able to migrate from the body 61 following implantation of the member 60.

While the depicted electrodes 62 are traditional relatively non-porous electrodes, it will be appreciated that one, some or all of the electrodes 62 could be formed from a porous material, such as a porous platinum.

Fig. 4 also depicts the entire body 61 as being formed from a porous material. In another embodiment, it will be appreciated that only one or more portions of the body 61 could be formed of such a material.

Where the body 61 is comprised of more than one portion, each of the portions can comprise the same material as the remainder of the elongate member but having a plurality of pores disposed therethrough. In one embodiment, the porous portions can comprise the same material as the remainder of the elongate member but which has undergone a processing step to render the portions foraminous.

In another embodiment, the porous portions of the body 61 can be formed from a different material to that of the remainder of the elongate member.

Figs. 6a and 6b depict a surface of an elongate member 71 that is surrounded by a sheath 72 fabricated from a porous material. As depicted, a quantity of bioactive substance 73 can be disposed beneath the sheath 72 and is free to migrate through the pores 74 in the sheath 72 in the direction of arrows A. In this embodiment, it will be appreciated that the elongate member 71 could have one or more of the features of the other elongate members described herein including those depicted in Figs. 2-4.

In each of the embodiments, each pore 81 of the porous material can be an individual pore within the portion, making no interconnection with another pore in the portion such as is depicted in Fig. 8. In Fig. 8, each of the pores 81 are aligned and equally spaced with respect to each other.

As depicted in Fig. 9, the porosity can be in essence in three dimensions with some or all of the pores 91 in a porous portion being interconnected in some way.

In some or each of the porous portions, at least some of the pores or each pore of the porous portion can be at least substantially uniform in cross-sectional shape relative to each other. In another embodiment, the pores can vary in cross-sectional shape from one to at least some of the others.

In some or each of the porous portions, at least some of the pores or each pore of the porous portion can be substantially uniform in diameter. In another embodiment, the pores can vary in diameter from one to at least some of the others.

In some or each of the porous portions, at least some of the pores or each pore of the porous portion can be of a substantially constant diameter along its length. In another embodiment, at least some of the pores or each pore can vary in diameter along its length.

In some or each of the porous portions, at least some of the pores or each pore of the porous portion can have a substantially uniform cross-sectional shape along its length. In another embodiment, at least some of the pores or each pore can vary in cross-sectional shape along its length.

In some or each of the porous portions, at least some of the pores or each pore of the porous portion can be of a substantially constant length. In another embodiment, at least some of the pores or each pore can vary in length relative to at least some of the others in that portion. In one embodiment, at least some of the pores can have relatively extended lengths compared to other pores in that portion.

In some or each of the porous portions, at least some of the pores or each pores of the porous portion can be at least substantially linear, such as respective pores 100 and 101 depicted in Fig. 7a and 7b. In another embodiment, at least some of the pores or each pores of the porous portion can be non-linear such as pore 102 depicted in Fig. 7c.

In some or each of the porous portions, at least some of the porous portions or each porous portion can have substantially the same of pores per unit area. In another embodiment, at least some of the porous portions or each porous portion can have differing number of pores per unit area relative to that of at least some of the other porous portions.

In some or each of the porous portions, at least some of the pores in one, some or each of the porous portions can have relatively smooth internal walls, such as pore 100 depicted in Fig. 7a. In another embodiment, at least some of the pores in one, some or each of the porous portions can have rippled internal walls, such as pore 101 depicted in Fig. 7b. The ripples can have a suitably small dimension to preferably at least substantially prevent wetting of the cavities thereby minimising friction between the bioactive substance and the walls.

The nature of the porosity between separate porous portions of the device may be the same or vary from one to at least some or all of the other portions. For example, the dimension of the pores of a porous portion relatively

close to the distal end of the elongate member may be different to the dimensions of the pores of a porous portion that is relatively close to the proximal end of the elongate member. In this embodiment, the portion relatively closer to the distal end can have pores having a diameter and/or length greater than the pores of the porous portion relatively closer to the proximal end of the elongate member. In another embodiment, the relative porosity of different portions can be essentially random.

In some or each of the porous portions, at least some of the pores of the porous portion can be preferably adapted to be at least substantially closed when the elongate member is at least substantially straight thereby preventing migration of any bioactive substance held within said at least some pores from these pores. See, for example Fig. 5a which depicts pores 103 as adopting a closed configuration when the elongate member is straight. On adopting a curved configuration, the pores 103 are adapted to at least partially open allowing migration of the bioactive substance therefrom, as represented by arrows B.

In this invention, the bioactive substances can be free to simply migrate from the pores of the porous portions following implantation of the device. In another embodiment, the bioactive substance can be dispersed in an ionic fluid that is preferably caused to migrate from the pores on application of a suitable electrical field thereto. In another embodiment, the bioactive substance can be dispersed in an ionic solution that is allowed to diffuse from the pores and/or be expelled therefrom under application of a suitable electric field.

In one embodiment, the bioactive substance can be dispersed in a suitable fluid. In one embodiment, the bioactive substance can comprise a steroid. In another embodiment, the bioactive substance can perform a function of reducing the resting neuron potential of neurons within the cochlea. The use of such substances can result in less energy being required to excite the neurons and cause stimulation.

In the present invention, the at least one bioactive substance can be delivered to a desired site of action within a cochlea using a device as described herein. The method preferably comprises the steps of:

forming a cochleostomy;

inserting the elongate member as described herein through the cochleostomy;

allowing or causing the bioactive substance to migrate from the elongate member into the cochlea.

In this method, the pores of the device are at least partially filled by dipping the elongate member in the bioactive substance for a suitable time period. This step can be performed immediately after manufacture of the elongate member. In another embodiment, the step can be performed just prior to implantation of the member into the implantee.

The provision of a system for delivering a pharmaceutical substance in the cochlea that promotes healing and/or more efficient neural stimulation while preventing the formation of substantial scar tissue in the cochlea, enhances the likelihood of successful long-term placement of the elongate member in the cochlea and subsequent successful use of the cochlear implant by the implantee.

While the preferred embodiment of the invention has been described in conjunction with a cochlear implant, it is to be understood that the present invention has wider application to other implantable electrodes, such as electrodes used with pacemakers.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this twenty ninth day of November 2002

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

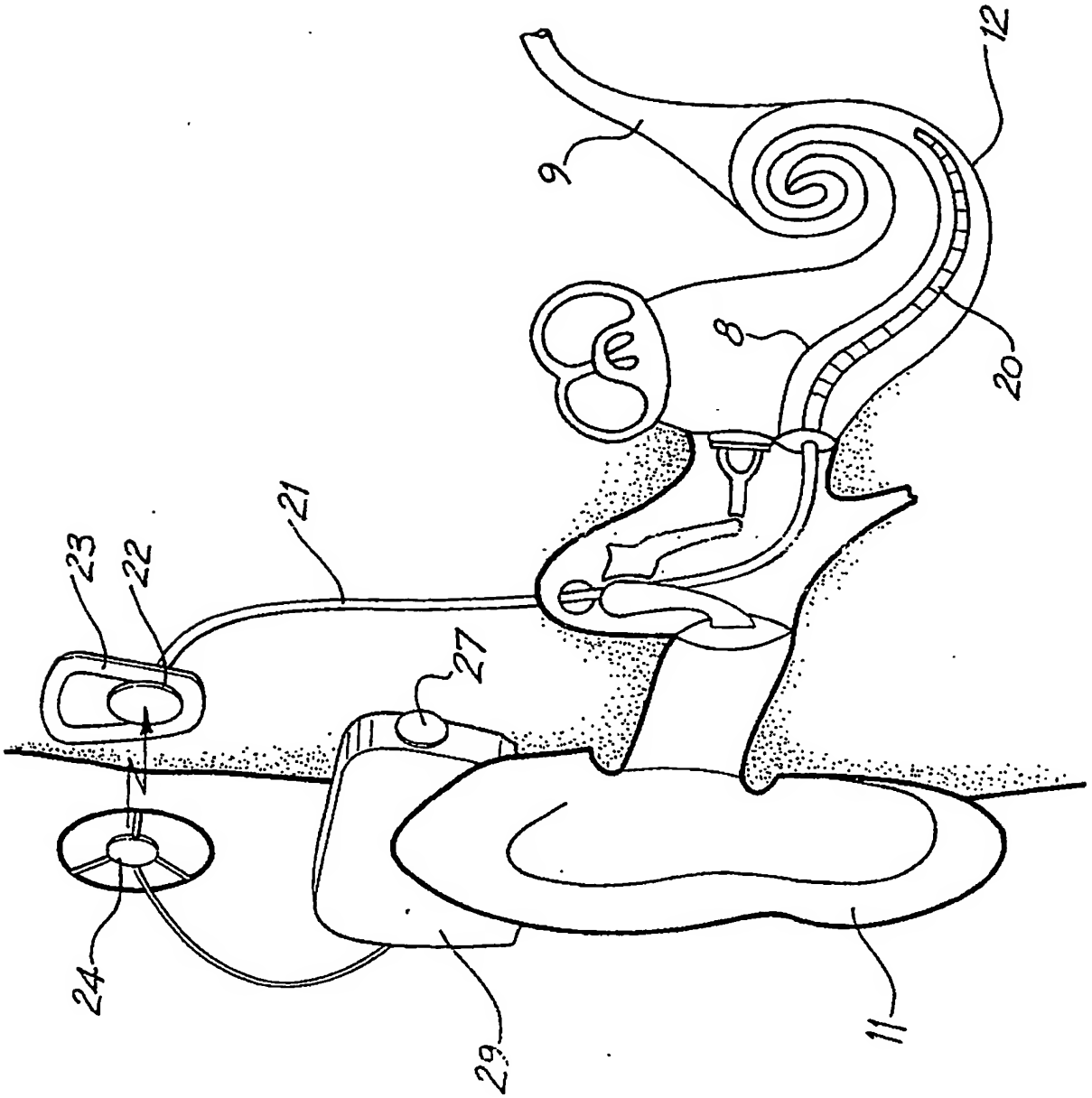

FIG. 1

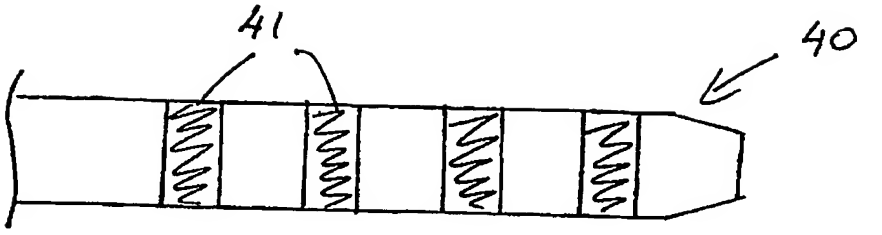

Fig. 2

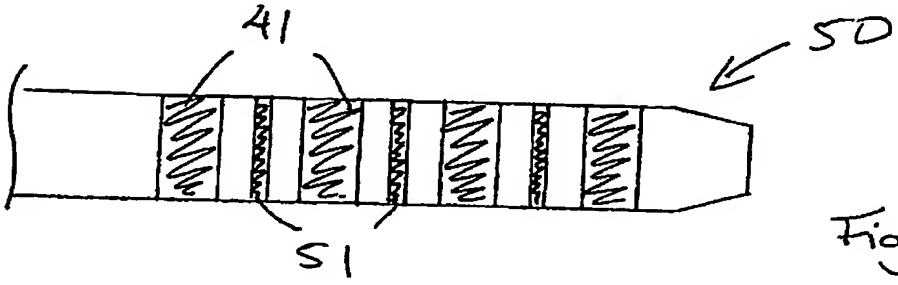

Fig. 3

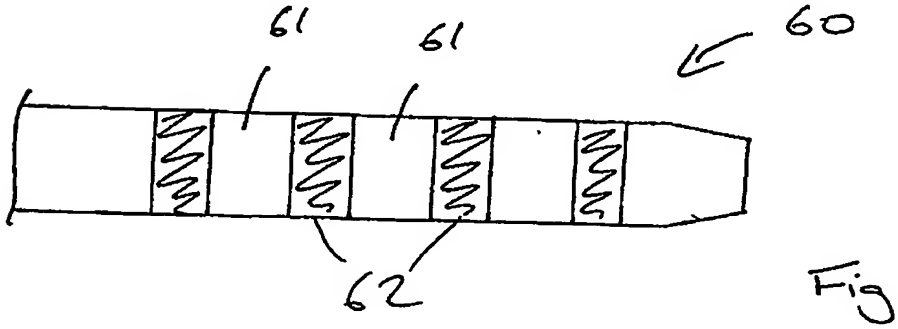

Fig. 4

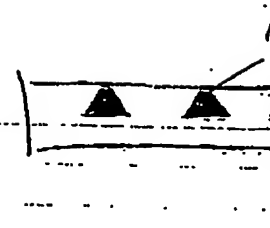

Fig. 5a

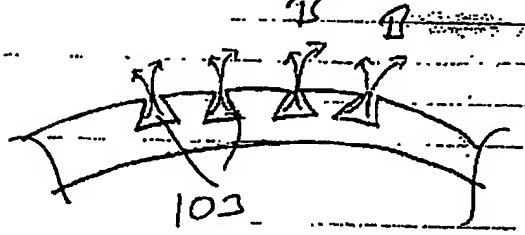

Fig. 5b

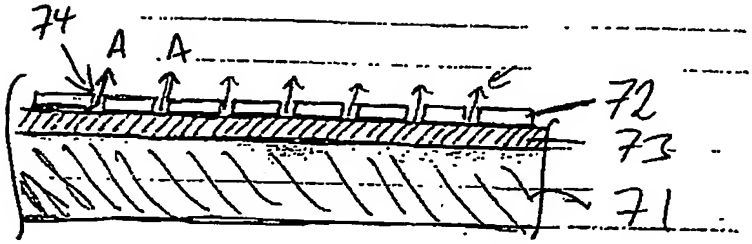

Fig. 6a

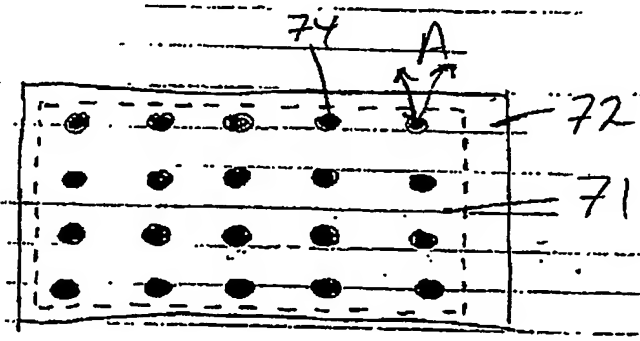

Fig. 6b

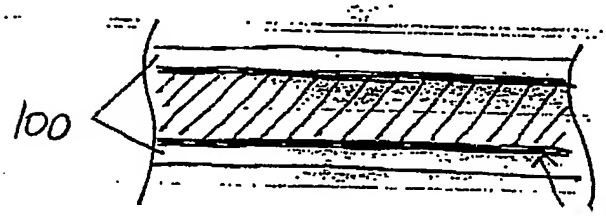

Fig. 7a

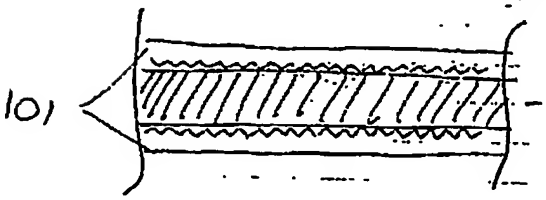

Fig. 7b

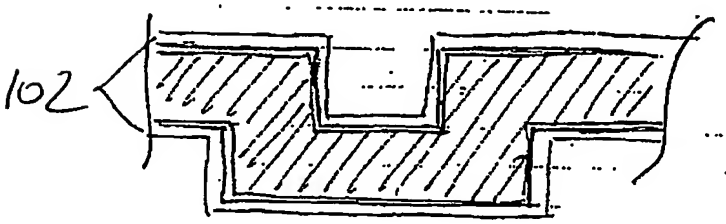

Fig. 7c

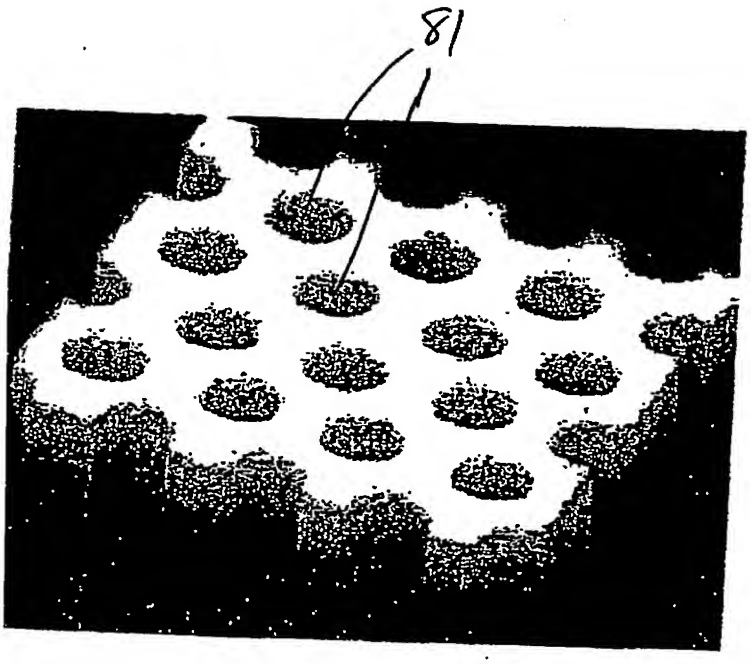

Fig. 8

Fig. 9